

Nesina Met[®]

Alogliptin (as benzoate)/ Metformin hydrochloride

Consumer Medicine Information (CMI)

What is in this leaflet

This leaflet answers some common questions about Nesina Met.

It does not contain all the available information. It does not take the place of talking to your doctor, pharmacist or diabetes educator.

The information in this leaflet was last updated on the date listed on the final page. More recent information on the medicine may be available. You should ensure that you speak to your pharmacist or doctor to obtain the most up to date information on this medicine. You can also download the most up to date leaflet from <https://www.ebs.tga.gov.au/>.

Those updates may contain important information about the medicine and its use of which you should be aware.

All medicines have risks and benefits. Your doctor has weighed the risks of you taking this medicine against the benefits they expect it will have for you.

If you have any concerns about taking this medicine, ask your doctor or pharmacist.

Keep this leaflet with the medicine.

You may need to read it again.

What Nesina Met is used for

Nesina Met is used to lower blood sugar levels in adults with type 2 diabetes mellitus.

Nesina Met is used when your blood sugar cannot be adequately controlled by diet, exercise and other anti-diabetic medicines such as metformin; metformin and insulin or metformin and medicines known as thiazolidinediones (e.g. pioglitazone).

If you are already taking both alogliptin and metformin as separate tablets, Nesina Met can replace them in one tablet.

Nesina Met is not for patients with type 1 diabetes mellitus or diabetic ketoacidosis (increased ketones in blood or urine).

It is important that you continue to follow the advice on diet and exercise that your doctor or diabetes educator has given you.

Type 2 Diabetes mellitus

Type 2 diabetes is also called non-insulin-dependent diabetes mellitus (NIDDM).

Type 2 diabetes develops if the body does not make enough insulin, or if the insulin that your body makes does not work as well as it should. It can also develop if the body produces too much glucagon.

Insulin is a hormone which helps to lower the level of sugar in your blood, especially after meals. Glucagon is another hormone which triggers the production of sugar by the liver, causing the blood sugar to rise. The pancreas makes both of these hormones.

If your blood glucose is not properly controlled, you may experience hypoglycaemia (low blood glucose) or hyperglycaemia (high blood glucose). High blood glucose can lead to serious problems with your heart, eyes, circulation and/or kidneys.

The main goal of treating diabetes is to lower your blood sugar to a level deemed appropriate by your doctor. Lowering and controlling blood sugar may help prevent or delay complications of diabetes.

How Nesina Met works

Nesina Met contain two different medicines called alogliptin and metformin in one tablet:

- alogliptin belongs to a group of medicines called DPP-4 inhibitors (dipeptidyl peptidase-4 inhibitors). Alogliptin works to increase the levels of insulin in the body after a meal and decrease the amount of sugar in the body.

- metformin belongs to a group of medicines called biguanides which also help to lower blood sugar by lowering the amount of sugar made in the liver and helping insulin to work more effectively.

Both of these groups of medicines are known as "oral antidiabetics". Alogliptin and metformin work together to control blood sugar levels in patients with type 2 diabetes mellitus.

Ask your doctor or pharmacist if you have any questions about why it has been prescribed for you.

This medicine is only available with a doctor's prescription.

This medicine is not addictive.

Before you take it

When you must not take it

Do not take Nesina Met if

- **you have a condition called metabolic acidosis or have had diabetic ketoacidosis (increased ketones in your blood or urine).**

Ketoacidosis is a serious complication of poorly controlled diabetes which can lead to a diabetic pre-coma. Symptoms include excessive thirst, frequent urination, loss of appetite, nausea or vomiting and rapid weight loss.

- **you are going to get an injection of dye or contrast agents for an x-ray procedure.**

Nesina Met will need to be stopped for a short time. Talk with your doctor about when you should stop Nesina Met and when you should start Nesina Met again.

- **you are allergic to alogliptin or metformin (the active ingredients in Nesina Met) or any of the ingredients listed at the end of this leaflet.**

Some symptoms of an allergic reaction include skin rash, itching, shortness of breath or swelling of the face, lips or tongue, which may cause difficulty in swallowing or breathing.

Do not give Nesina Met to a child or adolescent.

Nesina Met is not recommended for children and adolescents under 18 years due to the lack of data in these patients.

Do not take it after the expiry date printed on the pack.

The expiry date refers to the last day of that month. If you take it after the expiry date has passed, it may not work as well.

Do not take it if the packaging is torn or shows signs of tampering.

Before you start to take it

Discard any other medicines containing metformin or alogliptin that your doctor may have prescribed to you in the past and that you may still have in your possession.

Nesina Met contains metformin and alogliptin. If you have more than one medicine containing these ingredients in your possession you may accidentally take too much (overdose). Accidentally taking too much metformin can cause a very serious side effect called lactic acidosis.

Accidental metformin overdosing is a significant safety risk.

Ask your doctor or pharmacist if you are unsure if you have any other medicines containing metformin or alogliptin.

Metformin is sold under many different brand names in Australia. Your doctor or pharmacist will know which other medicines also contain metformin. Alogliptin is sold in Australia under the brand NESINA.

Before you take Nesina Met, tell your doctor if you:

- **have type 1 diabetes, also called insulin-dependent diabetes mellitus (IDDM) or juvenile onset diabetes, where the body does not produce enough insulin**
- **have diabetic ketoacidosis, a complication of diabetes where chemicals called ketones build up in the body due to very low insulin levels**
- **have kidneys problems**

Nesina Met should not be used in individuals with certain kidney problems.

- **have liver problems**

- **have heart problems**
- **have any other medical conditions**
- **are older than 80 years**

You should not take Nesina Met unless your kidneys have been checked and they are normal.

- **drink alcohol excessively either very often, or from time to time ("binge" drinking)**
- **have allergies to any other medicines or any other substances, such as foods, preservatives or dyes**

Your doctor will want to know if you are prone to allergies.

If you are not sure whether any of the above conditions apply to you, your doctor can advise you.

Tell your doctor if you are pregnant or intend to become pregnant.

Like most medicines of this kind, Nesina Met is not recommended to be used during pregnancy. If you are pregnant, talk with your doctor about the best way to control your blood sugar while you are pregnant.

Tell your doctor if you are breastfeeding or planning to breastfeed.

It is not known whether Nesina Met passes into breast milk. Talk with your doctor about the best way to feed your baby if you are taking Nesina Met.

If you have not told your doctor about any of the above, tell him/her before you take Nesina Met.

Taking other medicines

Tell your doctor or pharmacist if you are taking any other medicines, including any that you buy without a prescription from your pharmacy, supermarket or health food store.

Tell your doctor or pharmacist if you are taking any of the following:

- **corticosteroids (e.g. hydrocortisone, prednisolone), used to treat inflammation**
- **cimetidine, used to treat stomach problems**
- **bronchodilators (beta-2 agonists) which are used to treat asthma (e.g. salbutamol, terbutaline)**
- **ACE inhibitors, used to treat high blood pressure (e.g. ramipril, lisinopril, enalapril)**
- **diuretics, also called fluid tablets which increase urine production**
- **cationic drugs (e.g., amiloride, digoxin, morphine, procainamide, quinidine, quinine, ranitidine, triamterene, trimethoprim, and vancomycin)**
- **other drugs that tend to produce hyperglycaemia (high blood sugar) and may lead to a loss of blood sugar control. Some example of drugs that can increase the**

blood sugar include: phenothiazines, thyroid products, oestrogens or oestrogens plus progestogen, oral contraceptives, phenytoin, nicotinic acid, isoniazid

- **iodinated contrast agents or medicines containing alcohol**

How to take it

Follow all directions given to you by your doctor and pharmacist carefully.

They may differ from the information contained in this leaflet. If you do not understand the instructions on the label, ask your doctor or pharmacist for help.

How much to take

Your doctor will tell you exactly how much Nesina Met you need to take.

The amount of Nesina Met will vary depending on your condition and the doses you currently take of metformin alone, metformin in combination with a thiazolidinedione (e.g. pioglitazone), insulin and/or individual tablets of alogliptin and metformin.

The usual dose is one tablet twice a day.

Ask your doctor or pharmacist if you are unsure of the correct dose for you.

How to take it

Swallow your tablet whole with water.

You should take this medicine with food to reduce your chance of an upset stomach.

When to take it

Take your medicine at about the same time each day.

Taking it at the same time each day will have the best effect. It will also help you remember when to take it.

How long to take it

Continue taking your medicine for as long as your doctor tells you to.

It is important to keep taking your medicine even if you feel well.

Your doctor will check your progress and monitor your blood sugar levels to make sure the medicine is working and will discuss with you how long your treatment should continue for.

Diet and exercise can help your body use its blood sugar better. It is important to stay on your doctor's or diabetic educator's recommended diet, exercise and weight loss program while taking Nesina Met.

Ask your doctor or pharmacist if you are not sure how long to take the medicine for.

If you forget to take it

If you forget to take a dose, take it as soon as you remember it, and then go back to taking it as you would normally.

Do not take a double dose (two doses at the same time) to make up for the dose that you missed.

This may increase the chance of getting an unwanted side effect.

If it is almost time for your next dose, skip the dose you missed and take your next dose when you are meant to.

If you are not sure what to do, ask your doctor or pharmacist.

If you have trouble remembering when to take your medicine, ask your pharmacist for some hints.

If you take too much (overdose)

Immediately telephone your doctor or the Poisons Information Centre (telephone 13 11 26), or go to Accident and Emergency at your nearest hospital, if you think you or anyone else may have taken too much Nesina Met. Take this leaflet or some tablets with you so that your doctor knows exactly what you have taken.

Do this even if there are no signs of discomfort or poisoning.

You may need urgent medical attention.

While you are taking it

Things you must do

Tell all the doctors, dentists and pharmacists who are treating you that you are taking Nesina Met.

If you are about to start on a new medicine, tell your doctor and pharmacist that you are taking Nesina Met.

If you become pregnant while you are taking this medicine, tell your doctor immediately.

Like most medicines of this kind, Nesina Met is not recommended to be used during pregnancy. Talk with your doctor about the best way to control your blood sugar while you are pregnant.

Carefully follow your doctor's and/or dietician's advice on diet, drinking alcohol and exercise.

Keep all of your doctor's appointments so that your progress can be checked.

Your doctor will do regular checks to help prevent you from having side effects from the medicine or developing serious complications of diabetes.

Your doctor will do blood tests to check how well your kidneys are working before and/or during your treatment with Nesina Met.

Make sure you check your blood glucose levels regularly.

This is the best way to tell if your diabetes is being controlled properly. Your doctor or diabetes educator will show you how and when to do this.

If you become ill or experience extra stress, injury, fever, infection or need surgery, tell your doctor.

Your blood glucose may become difficult to control at these times.

Make sure you keep enough medicine to last over weekends and holidays.

It is important to keep your blood glucose controlled at all times to prevent serious complications of diabetes from happening.

Things you must not do

Do not take more than the recommended dose unless your doctor or pharmacist tells you to.

Do not give this medicine to anyone else, even if they have the same condition as you.

Do not use this medicine to treat any other complaints unless your doctor tells you to.

Do not stop taking Nesina Met without checking with your doctor.

Do not skip meals while taking Nesina Met.

Do not take this medicine with alcohol as you could be at greater risk of developing lactic acidosis, a serious complication which must be treated in a hospital.

Things to be careful of

Be careful driving, operating machinery or doing jobs that require you to be alert until you know how this medicine affects you.

If your blood glucose level becomes too low, you may feel dizzy, lightheaded, weak or tired and your reaction time may be slower than usual.

If you have any of these symptoms, do not drive or do anything else that could be dangerous.

Be careful when doing any of the following things, which increase the risk of your blood glucose becoming too low:

- drinking alcohol
- not eating enough
- doing unexpected or vigorous exercise

Side effects

All medicines have some unwanted side effects. Sometimes they are serious, but most of the time they are not.

Your doctor has weighed the risks of using this medicine against the benefits they expect it will have for you.

Do not be alarmed by this list of possible side effects.

You may not experience any of them.

Tell your doctor or pharmacist as soon as possible if you do not feel well while you are taking Nesina Met.

Tell your doctor or pharmacist if you notice any of the following and they worry you:

- stomach pain
- nausea
- vomiting
- loss of appetite
- indigestion, heartburn
- a metallic taste in your mouth
- diarrhoea
- headache
- cold-like symptoms such as stuffy or runny nose, sore throat, feeling tired
- rash
- itchy skin with or without hives
- joint pain

Tell your doctor immediately if you notice any of the following:

- blisters or the breakdown of the outer layer of your skin (erosion).

Some people who take medicines called DPP-4 inhibitors, like alogliptin, may develop a skin reaction called bullous pemphigoid, that may require treatment in a hospital. Your doctor may tell you to stop taking Nesina Met.

If any of the following happen, stop taking this medicine and tell your doctor immediately, or go to Accident and Emergency at your nearest hospital:

- **Symptoms of allergic reaction.**

The symptoms may include: a rash, hives, swallowing or breathing problems, swelling of your lips, face, throat or tongue and feeling faint.

- **A severe allergic reaction including general itching and feeling of heat – especially affecting the scalp, mouth, throat, palms of hands or soles of feet (Stevens-Johnson syndrome).**

This severe allergic reaction has been reported in a very small number of patients.

- **Severe and persistent pain around the top of your stomach which might reach into your back, often with nausea and vomiting.**

This could be a sign of an inflamed pancreas (pancreatitis).

- **Yellowing of your skin or the whites of your eyes, nausea, loss of appetite, unusual or unexplained tiredness, dark urine**

These could be signs of liver problems.

- **Symptoms of low blood sugar (hypoglycaemia): trembling, sweating, anxiety, blurred vision, tingling lips, paleness, mood change or feeling confused.**

Hypoglycaemia may occur when Nesina Met is taken in combination with insulin or sulphonylureas (e.g. gliclazide, glipizide, glimepiride, glibenclamide). Your blood sugar could fall below the normal level and can be increased by taking sugar. Your doctor, pharmacist or diabetes educator may have recommended that you carry some glucose tablets, sugar lumps, sweets, biscuits or sugary fruit juice.

These may be serious side effects of Nesina Met. You may need urgent medical attention.

In rare cases, metformin, one of the medicines in Nesina Met, can cause a serious side effect called lactic acidosis (build up of lactic acid in the blood).

Lactic acidosis is a medical emergency that can cause death and must be treated in the hospital. It can particularly affect patients whose kidneys are not working properly.

Stop taking Nesina Met and contact a doctor or go to Accident and Emergency immediately if you experience some of these symptoms:

- feeling cold or uncomfortable
- feeling tired or weak
- feeling dizzy or lightheaded
- severe nausea with or without vomiting
- abdominal pain
- muscle pain
- slow or irregular heartbeat
- unexplained weight loss
- rapid or difficult breathing
-

Tell your doctor or pharmacist if you notice anything else that is making you feel unwell.

Other side effects not listed above may occur in some consumers.

Ask your doctor or pharmacist to answer any questions you may have.

After taking it

Storage

Keep your tablets in the blister pack until it is time to take them.

Keep the medicine in a cool, dry place where the temperature stays below 25°C.

Do not store it or any other medicine in the bathroom, near a sink, or on a windowsill.

Do not leave it in the car.

Heat and damp can destroy some medicines.

Keep it where children cannot reach it.

A locked cupboard at least one-and-a-half metres above the ground is a good place to store medicines.

Disposal

If your doctor tells you to stop taking Nesina Met, or the medicine has passed its expiry date, ask your pharmacist what to do with any tablets left over.

Product description

What it looks like

Nesina Met comes in three strengths of tablets:

- Nesina Met 12.5 mg/500 mg film coated tablets are pale yellow, oblong, biconvex, with "12.5/500" debossed on one side and "322M" debossed on the other side
- Nesina Met 12.5 mg/850 mg film coated tablets are light yellow, oblong, biconvex, with "12.5/850" debossed on one side and "322M" debossed on the other side.
- Nesina Met 12.5 mg/1000 mg film coated tablets are pale yellow, oblong, biconvex, with "12.5/1000" debossed on one side and "322M" debossed on the other side.

Nesina Met is available in blister packs of 14 (sample) and 56 tablets.

Ingredients

Active Ingredient:

The active substances in Nesina Met are alogliptin (as benzoate) and metformin hydrochloride.

Each tablet contains

- alogliptin benzoate equivalent to 12.5 mg alogliptin free base and
 - 500 mg metformin hydrochloride (12.5 mg/500 mg)
- or**
- 850 mg metformin hydrochloride (12.5 mg/850 mg)
- or**

- 1000 mg metformin hydrochloride (12.5 mg/1000 mg).

Inactive Ingredients:

Nesina Met tablets also contain

- mannitol
- microcrystalline cellulose
- povidone
- crospovidone
- magnesium stearate
- hypromellose
- purified talc
- titanium dioxide
- iron oxide yellow (CI77492)

Nesina Met does not contain gluten, sucrose or lactose.

Sponsor

Takeda Pharmaceuticals Australia Pty Ltd

Level 5

2 Chifley Square

Sydney NSW 2000

Ph: 1800 675 957

Distributor

Nesina Met is distributed in Australia by:

Servier Laboratories (Aust.) Pty Ltd

PO Box 196

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Hawthorn, VIC 3122

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Australian Registration Numbers

Nesina Met 12.5mg/500 mg tablets: AUST R 202308

Nesina Met 12.5mg/850 mg tablets: AUST R 202306

Nesina Met 12.5mg/1000 mg tablets: AUST R 202309

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